## II. Rej ction Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-6 and 8-49 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,993,491 to *Lim et. al.* ("*Lim*") in view of WO 99/17730 to *de la Mettrie et. al.* ("*de la Mettrie*") and U.S. Patent No. 5,254,333 to *Kajino et. al.* ("*Kajino*"). Applicants respectfully traverse this rejection as the Examiner has failed to provide sufficient evidence of a *prima facie* case of obviousness.

In the rejection, the Examiner relies on the primary reference, *Lim*, for disclosing "1-(4-aminophenyl) pyrrolidine compounds having a formulae similar to the claimed formula . . . ." Office Action, page 2. To substantiate the rejection, he points to formulae 1, 1a, and 2 in column 4 of *Lim*. The Examiner acknowledges, however, that *Lim* does not specifically teach or suggest the use of thickening polymers comprising at least one sugar unit, enzymatic oxidizing systems as oxidizing agents, or direct dyes. Office Action, page 3.

To remedy *Lim's* deficient disclosure, the Examiner relies on the teachings of *Kajino* and *de la Mettrie*. According to the Examiner, *Kajino* teaches a "hair dyeing composition comprising from 0.05 to 20% of thickening polymers such as hydroxyethylcellulose, carboxymethylcellulose, guar gum, pertin [sic], and xanthan gum . . . . . . Office Action, page 3. *De la Mettrie*, according to the Examiner, teaches a hair dyeing composition comprising cationic direct dyes and an enzymatic oxidizing system, using enzymes such as pyranose oxidase and peroxidase. *Id*.

The Examiner concludes that "in view of the teachings of the secondary references, one having ordinary skill in the art would have been motivated to modify the

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primary reference by using [an] enzymatic oxidizing system as oxidizing agents, thickening polymers and direct dyes to make such a dyeing composition." *Id.* at 4. This modification would have been obvious because "one would expect the use of oxidizing enzymes, thickening polymers and direct dyes as taught by *de la Mettrie* and *Kajino* would be similarly useful and applicable to the analogous composition taught by *Lim*." *Id.* As discussed below, the Applicants respectfully disagree with the Examiner's rationale.

According to M.P.E.P. § 2143, an Examiner carries the initial burden of establishing a *prima facie* case of obviousness. In so doing, he must demonstrate that certain criteria have been met. He must point to some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings. Further, he must provide evidence of why one of ordinary skill in the art would have had a reasonable expectation that such a combination would lead to a successful result. Here, the Examiner has failed to set forth the necessary evidence to establish either one of these criteria.

## 1. No Motivation to Modify Lim With the Secondary References Exists

In the Applicants' view, nothing in *Kajino* or *de la Mettrie* would have motivated one of ordinary skill in the art to modify *Lim* with the secondary references. The Examiner, however, attempts to support this modification by alleging obviousness based on similar utility and applicability. Office Action, page 3. But such an unsubstantiated allegation cannot support a § 103(a) rejection.

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In fact, the M.P.E.P. states that "the examiner bears the initial burden of <u>factually</u> supporting any *prima facie* case of obviousness." M.P.E.P. § 2142 (emphasis added). The Federal Circuit has further explained that the factual inquiry whether to combine references must be "thorough and searching" and "based on objective evidence in the record." *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). After this factual inquiry, an examiner must then set forth "clear and particular" evidence of a teaching, suggestion, or motivation to combine the reference teachings; broad or conclusory statements will not suffice. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). In this case, the Examiner has failed to set forth any evidence, let alone "clear and particular evidence," of a motivation or suggestion to modify the *Lim* reference with the secondary references.

The present invention relates to compositions and methods for the oxidation dyeing of keratinous fibers comprising, in a medium suitable for dyeing, at least one oxidation dye precursor chosen from 1-(4-aminophenyl) pyrrolidines of formula (I) and at least one thickening polymer comprising at least one sugar unit. As noted above, the Examiner cites *Lim* for its teaching of the claimed pyrrolidines and, *inter alia*, a broad teaching of polymeric thickeners.

An analysis of *Lim* demonstrates the weakness of the Examiner's arguments. For instance, although *Lim* does disclose that thickeners can be used in its invention, it merely teaches that "thickeners such as . . . starch, [and] cellulose derivatives . . . may be formulated into the compositions of the invention." Lim, col. 8, lines 18-22. It then provides various examples of the types of thickeners that could be included in the

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invention. *Lim*, col. 8, line 18-col. 9, line 4. Notably however, *Lim* does not include any examples of starch or cellulose derivatives. Instead, it lists various types of fatty acid soaps and associative thickeners such as Aculyn-33 and Aculyn-44 as examples of useful thickeners. *Id.*, col. 8, lines 48-50. Thus, the thickeners disclosed by *Lim* do not particularly suggest a thickening polymer comprising at least one sugar unit.

Moreover, an Examiner must consider a prior art reference in its entirety.

M.P.E.P. § 2141.02. *Lim* discloses an extensive list of possible thickeners, therefore, when one skilled in the art considered *Lim*, she would also necessarily consider all other thickeners taught by *Lim*, including the ones that fell outside the scope of Applicants' claims. Thus, with the exception of a vague reference to cellulose derivatives, *Lim* provides no suggestion or motivation to add a thickening polymer comprising at least one sugar unit to its hair dye system.

To make up for *Lim's* deficiencies, the Examiner improperly relies on *Kajino*, a reference directed towards a non-oxidative hair dye composition, to provide the suggestion to modify *Lim* to include a thickener comprising at least one sugar unit. *Kajino*, however, has nothing to do with oxidative hair dyes and in fact only mentions them when it discusses the drawbacks of the oxidation hair dye process. *Id.*, col. 1, lines 41-45. Accordingly, when considering *Kajino* together with the oxidative hair dyes of *Lim*, a skilled artisan would not only have to exclude one of *Kajino*'s core ingredients (the acidic dye), but also consider the fact that it teaches away from the use of oxidation bases to color the hair.

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Because *Kajino* does not suggest or even hint that the presently claimed thickener can be combined with the presently claimed oxidation base, the Examiner has improperly used this reference to substantiate the § 103 rejection. Nothing in *Kajino* suggests the desirability of using the presently claimed thickener in conjunction with the presently claimed oxidation base. *Winner Int'l. Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 (Fed. Cir. 2000) (noting that the prior art must suggest the desirability of the proposed combination). Thus, *Kajino* does not provide the necessary guidance to modify *Lim* as required to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Finally, because *Lim* does not teach the use of cationic direct dyes or an enzymatic oxidizing system, the Examiner relies on the *de la Mettrie* reference, which does disclose such ingredients. The oxidizing agents used in Lim's dyeing compositions include "hydrogen peroxide, urea peroxide, melamine peroxide, perborates and percarbonates . . . ." *Lim*, col. 9, lines 10-14. *Lim* does not even remotely suggest that direct dyes or an enzymatic oxidizing system can be used in its hair dye composition. Indeed, *Lim* teaches that "hydrogen peroxide is a preferred oxidizing compound for use as a developer with the primary intermediate and coupler dye precursors of the invention." *Lim*, col. 9, lines 9-12. Therefore, because *Lim's* composition functions perfectly with its specific oxidizing system, no reason would have existed to modify the invention to incorporate an enzymatic oxidizing system.

Thus, the Examiner has not sustained his burden of showing a suggestion or motivation to modify *Lim*. Instead, the Examiner has plainly used the present invention

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as a guide to pick and choose elements from the prior art, i.e., thickeners and enzymatic dye systems. As the Federal Circuit has stated, "a rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations, rather particular findings must be made as to the reason why the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). The Examiner, however, has made no such findings here. Thus, for at least this reason, Applicants respectfully request that the Examiner withdraw the rejection.

## 2. No Reasonable Expectation of Success

Not only is there no motivation to combine the *Lim*, *Kajino*, and *de la Mettrie* references, there is substantial evidence that the art of oxidative hair dyeing is generally unpredictable, thus further weakening the Examiner's argument for combining the relevant teachings. Given this unpredictability, a skilled artisan would not have considered it obvious to combine 1-(4-aminophenyl) pyrrolidine, a thickening polymer comprising at least one sugar unit, and an enzymatic oxidizing system as an oxidizing agent. *See*, e.g., claim 29.

Hair dye chemistry is unpredictable largely because there are a number of variables one must consider when creating oxidative hair dyes. *Lim* teaches that, "[i]n order for procedures using permanent oxidative dyes to work properly, a number of parameters and conditions are important to consider in the use of the permanent hair dye intermediates in admixtures with couplers in hair color preparations for human hair. *Lim*, col. 1, lines 42-46. *Lim* then lists these parameters, which include, final color and

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color intensity after application to the hair, wash fastness and light fastness of the resulting dye, the resistance of the dye to perspiration, as well as to various treatments, such as permanent wave, straightening, shampooing, conditioning and rubbing. *Id.* at lines 45-52. Further, "the dye must have virtually no allergenicity or dermal or systemic toxicity." *Id.* at lines 52-53.

Thus, it is unlikely, given the large number of variables to consider in creating a successful hair dye, that a skilled artisan could reasonably predict a successful combination of oxidation bases, thickeners, and oxidizing systems. In fact, *Lim* notes that "[i]t has been found surprisingly that dyes produced by coupling the compound 1 or 1a with conventional couplers are different from those derived from coupling 1-(4-aminophenyl) pyrrolidine or N,N-bis(2-hydroxyethyl)-p-phenyldiamine 3 with the same couplers in spite of the fact that the compounds are structurally similar to one another." *Lim*, col. 3, line 65-col. 4, line 3. Thus, merely selecting various elements from the prior art does not necessarily guarantee the desired result, and, as *Lim* notes, even structurally similar primary intermediates can have different dyeing effects. By rejecting the claims based on obviousness, the Examiner fails to take into account the great unpredictability of the oxidative hair dye process.

Given this, there would have been no reasonable expectation that combining (1) an oxidation base that is only structurally similar to the compounds taught by *Lim* with (2) a thickener comprising at least one sugar unit (disclosed in prior art related to a non-oxidative dye composition) and (3) an oxidizing system taught by *de la Mettrie* would result in workable hair dye compositions. Further, without some reasonable expectation

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of success, the Examiner has not established a *prima facie* case of obviousness. Thus, for at least this reason, the Applicants respectfully request that this rejection be withdrawn.

## III. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: February 24, 2003

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